REMARKS

Claims 1-4, 7-12, 15-21 and 28-46 are currently pending. Claims 5-6, 13-14 and 22-27 have been previously cancelled. Claim 1has been amended. Claims 1 and 4 have been amended to incorporate the specific salmeterol salts of claim 6 into claim 1 and the propellant-free nature of the composition has been incorporated from claim 14 as well as including the specific nature of the combination as supported throughout and specifically on page 8, last paragraph of specification. No new matter has been introduced into the application by way of amendment.

Objection to the Specification:

The examiner has objected to the specification namely page 13, lines 34-36 to a the incorporation of foreign application or patent, or to a publication, i.e. WO 97/12687 as being improper. While not agreeing with the propriety of the Examiner's objection and solely to advance prosecution, Applicants have inserted the US Patent equivalents of the cited publication (which is in conformity with the rules governing incorporation by reference) and no new matter has been inserted into the application by way of amendment.

Rejection under 35 USC 112, second paragraph:

Claim 43 has been objected to as being improper for and not self-contained. Claim 43 has been amended to remove any reference to patent numbers and they have been replaced with the representation of the inhalers in those patent numbers, which are Figures Ia and Ib as indicated in the specification on page 13, lines 34-36. The propriety of referencing figures in claims is provided for in **MPEP 2173.05(s)**, Reference to Figures or Tables, which states: Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

Instantly, there is no practical way to defined the invention in words, it is more concise to incorporate by reference than duplicating the drawing as depicted in Figures 1a and 1b, hence, it is believed that these amendments are sufficient to overcome the aforementioned objections. Withdrawal of the objections is respectfully solicited.

Rejection under 35 USC 103(a):

(a) Rejection of claims 1-12, 14-22, 26-42 and 45-46 as being unpatentable over Hochrainer, et al and Wolf, et al. This rejection is respectfully traversed.

The Examiner contends that although the prior art references differ from the instant claims in that the prior art does not teach "1) the concomitant employment of these medicaments, and 2) administration levels of the medicaments", it would have been prima facie obvious to "combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose." In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

The Examiner has failed to establish a prima facie case of obviousness. The court states in In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987) that "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)."

The Examiner fails to provide a specific teaching in either Hochrainer or Wolf to the claimed combination. Moreover, there is no teaching, suggestion, or incentive in Hochrainer to modify the singly specifically expemlified composition containing formoterol, or those specifically claimed compositions containing formoterol, salbutamol and/or tiptropium by changing the composition to salmeterol optionally in one of its specific salt forms with tiotropium optionally in one of its specific forms. There is no rationale in the rejection that overcomes these deficiencies. Also, there is no teaching, suggestion, or incentive in Wolf to modify the salmeterol containing composition to a composition containing salmeterol optionally in one of its specific salt forms with tiotropium optionally in one of its specific forms.

In the absence of any support in Hochrainer or Wolf for the claimed combination, the examiner states on page 4 of the office action, beginning on the first line, that:
"It would have been prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be

used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-asthma agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980)."

The reliance on Kerhoven by the Examiner shows a belief that the decision is relevant. Applicant's respectfully disagree. The court in Kerhoven, states:
"It is prima facie obvious to combine two composition each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crookett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As this court explained in Crookett, the idea of combining them flows logically from their having been individually taught in the prior art. In the case at bar, appealed claims 2-4, 9 and 14 require no more than the mixing together of two conventional spray-dried detergents. Thus, these claims set forth prima facie obvious subject matter."

These, however, are not the facts here. Hochrainer provides a teaching and evidence for the use of the formulation in a "highly concentrated form", which is "not suitable for administration as such, but are converted to the formulation to be administered by additional measures. The reference goes on to discuss that the additional measures involve "dilution with a solvent to which additional additives, active substances or other auxillary agents can be optionally added." The primary focus of Hochrainer is to provide stable formulations that are highly concentrated in order to promote the storage of active-substance formulations. One of ordinary skill in the art would not have found obvious the combination of a tiotropium salt with a salmeterol salt that is to be used for first administration and would be expected to have characteristics that cause the composition to have a rapid onset of activity, long-lasting and reduce the central side effects of β-mimetics. Wolf provides a teaching and evidence to show the effects of salmeterol in powder form composition versus aerosol compositions. The reference makes no indication to the activity of salmeterol when combined with tiotropium or a salt thereof. Kerhoven is not applicable to these facts. See the discussion in opinion *Ex Parte Bokisa*, 1997 WL 1897871 (Bd.Pat.App & Interf., 1997).

In view of the foregoing, Applicants assert that the Examiner has failed to establish a *prima facie* case of obviousness.

Furthermore, even assuming, *arguendo*, that a *prima facie* case of obviousness could have been had been established against the combination of a tiotropium salt and a salt of salmeterol, applicants maintain that the unexpected beneficial and synergistic effects achieved by the combination of long-lasting anticholinergics such as a salt of tiotropium and long-lasting β-mimetics such as a salt of salmeterol evidenced by the attached 37 CFR 1.132 declaration as provided in co-pending case 09/568,880 (which is herein attached) would have overcome it. Withdrawal of the rejections is respectfully solicited.

Double Patenting:

Claims 1-4, 7-12, 15-21 and 28-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending application no. 10/736,264.

MPEP 804(I)(B), third paragraph states:
"If the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent". In view of the above amendments and remarks, Applicants believe that the provisional double patenting rejection is the only rejection that remains in the application, hence, the examiner should withdraw the rejection and permit the application to issue as a patent and maintain the double patenting rejection in the '264 application.

In view of the above amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance and earnestly request such action.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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